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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/687,951 | 10/13/2000 | Jeffrey I. Cleland | M-9177-US | 8871 |

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EXAMINER

KAM, CHIH MIN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1653

DATE MAILED: 12/31/2002

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/687,951

Applicant(s)

CLELAND ET AL.

Examiner

Chih-Min Kam

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17,20-23,25-31 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17,20-23,25-31 and 33-36 is/are rejected.
- 7) ☒ Claim(s) 36 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of the Claims

1. Claims 17, 20-23, 25-31 and 33-37 are pending.

Applicants' amendment filed on October 16, 2002 (Paper No. 20) is acknowledged, and applicants' response has been fully considered. Claims 17, 20, 21, 29, 30, 33 and 35 have been amended, claims 24 and 32 have been cancelled, and new claims 36 and 37 have been added.

Thus, claims 17, 20-23, 25-31 and 33-37 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous rejection of claim 20, under 35 U.S.C.112, first paragraph, is withdrawn in view of applicants' amendment to the claims in Paper No. 20.
3. The previous rejection of claims 24, 29, 30, 32, 33 and 35 under 35 U.S.C.112, second paragraph, is withdrawn in view of applicants' cancellation of the claim, and applicants' amendment to the claims in Paper No. 20.

Claim Rejections - 35 USC § 103

4. The previous rejection of claims 17, 20-28, 30, 31 and 34 under 35 U.S.C. 103(a) as being unpatentable over Machida *et al.* (EP 0,263,490) in view of syringe section (page T679) of Aldrich catalog (2000-2001), is withdrawn in view of applicants' cancellation of the claim, applicants' amendment to the claims, and applicants' response at pages 3-4 in Paper No. 20.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 20-23, 25-27, 30, 31, 33, 34 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 21-23, 25-31, 33, 34 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite because the specification appears to define hyaluronic acid (see page 4, lines 21+) as part of or as a biologically active agent (see the definition proffered at page 6, lines 10+ of the current specification). Thus, claim 21 and claims dependent thereof are indefinite as to whether hyaluronic acid is or is not part of an agent having in vivo activity, typically an activity that confers therapeutic, prophylactic, and/or diagnostic utility given the definition at page 4 of hyaluronic acid being found in the extracellular matrix of connective tissue. Thus, in claim 21, is item (a) included in item (b)(i) and/or (b) (ii)? For clarity, claim 28 should be cancelled in favor of inserting "polypeptide" in claim 21 in place of "agent". Claims 22, 23, 25-31, 33, 34 and 36 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

7. Claim 20 recites the limitation "biologically active agent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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8. Claims 21-23, 26, 27 and 34 are rejected under 35 U.S.C. 102(a) as anticipated by Pierre *et al.* (Fr 2,778,847, November 1999).

Pierre *et al.* teach an implant for sub-gingival injection comprising bio-resorbable microphages suspended in a physiological gel, wherein microspheres are made from a lactic-glycolic copolymer and poly(D,L-lactide-co-glycolide) copolymer, resomer RG502 and RG 756; the physiological gel is either 0.8% hyaluronic acid (claim 22) or its sodium salt (claim 34); and the microspheres contain an antiseptic or antibiotic such as hexetidine and metronidazole (abstract; page 1, lines 11-29; claims 21, 26, 27). The hyaluronic acid would be expected to be slowly dissolved in/at physiological pH solution and temperature (claim 23).

A copy of English translation of Fr 2,778,847 will be forward to applicant, once the Examiner receives it.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 17, 20, 21-23, 26-29, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pierre *et al.* (Fr 2,778,847, November 1999) taken with Mathiowitz *et al.* (U.S. Patent 5,985,354).

Pierre *et al.* teach an implant for sub-gingival injection comprising bio-resorbable microphages suspended in a physiological gel, wherein micro spheres are made from a lactic-glycolic copolymer and poly(D,L-lactide-co-glycolide) copolymer, resomer RG502 and RG 756; the physiological gel is either 0.8% hyaluronic acid (claim 22) or its sodium salt (claim 34); and the microspheres contain an antiseptic or antibiotic such as hexetidine and metronidazole (abstract; page 1, lines 11-29; claims 21, 26, 27). The hyaluronic acid would be expected to be slowly dissolved in/at physiological pH solution and temperature (claim 23). Pierre *et al.* also indicate the particle size of microphages is 20-100 microns which will pass through a 26-30 gauge needle for injection (abstract; page 3, lines 16-20; claim 20). However, Pierre *et al.* do not teach the use of polypeptide as the biological active substance in the microspheres. Mathiowitz *et al.* teach biological active substances such as enzymes, hormones or antibodies can be incorporated in the polymeric microsphere (column 8, lines 10-17; claim 17, 28, 29 and 35). At the time of invention was made, it would have been obvious to one of ordinary skill in the art using the biological active substance taught by Mathiowitz *et al.* to prepare the injectable formulation as taught by Pierre *et al.* to deliver various biological substances for therapeutic use. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

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9. Claims 36 and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

December 24, 2002

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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